UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

09 CV 0663

PATIENTS FOR MEDICAL JUSTICE, LTD.
488 Central Avenue
Suite A
Lancaster, New York 14086

Plaintiff

V.

UNITED STATES FOOD AND DRUG ADMINISTRATION (FDA)
5600 Fisher Lane
Rockville, Maryland 20857

Ms. Julie Zawisza
Assistant Commission

Dr. Margaret Hamburg
U.S. FDA Commissioner

Dr. Joshua M. Sharfstein
Deputy Commissioner
Transparency Task Force

Defendant

Civil Case No. _____

COMPLAINT

July 22 2009

Plaintiff, Patients for Medical Justice, LTD., as and for its Complaint, alleges as follows:

NATURE OF ACTION

1. This a civil action brought pursuant to FOIA 552 of the Freedom of Information Act for injunctive and other equitable relief and other appropriate relief seeking expedited processing (20 business days) and release of records requested by Plaintiff from the United States Food and Drug Administration (FDA).

2. This Freedom of Information lawsuit seeks the immediate disclosure of the **information submitted** in reference to the FDA documents and information **filed** by Closure Medical

Corporation; **Dermabond High Viscosity Line Extension Adhesive;** NuSil Technology; **Liquid Silicone Rubber MED-4870;** Rehau Inc.; - **Raumed Polyethylene Terephthalate Silicone Glue SI 1511**; and Guidant Corporation.

3. Plaintiffs believe the defibrillators experienced failures that caused serious injuries, additional surgeries, pain, suffering and death. Plaintiff submits that the defibrillators were experimental, investigational, non-FDA submitted, non-FDA approved, misbranded, toxic, carcinogenic, biological combination devices, and that the disclosures are in the public interest.

4. Jurisdiction of this Court is invoked pursuant to 552(a) (4) (B) and 552(a) (E) (iii) of the Freedom of information Act [5 U.S.C.A. 552 (a) (4) (B)] and [552 (a) (E) (iii)]; 28 U.S.C.A. 1331] (federal questions), and the equitable powers inherent in the courts of the United States.

5. Venue properly lies in the district pursuant to 28 U.S.C.A. 1391 (e). 5 U.S.C.A. 552 (a) (4) (B).

PARTIES

6. Plaintiff, Patients for Medical Justice, Ltd. (Hereinafter referred to as PFMJ) is a New York State not-for-profit corporation with office and principal place of business at 488 Central Avenue, Suite A Lancaster, New York 14086. PFMJ's purpose is to collect data on medical procedures and devices in order to educate and inform the general public of the discovery of any non FDA submitted Life Sustaining medical devices.

7. Defendant, United States Food and Drug Administration (hereinafter referred to as FDA) is an agency within the United States Department of Health and Human Services which is an agency of the executive branch of the United States and is a proper party within the meaning of 5 U.S.C.A. 702 and 703 as amended.

8. FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, combination biological devices, our nation's food supply, cosmetics and products that emit radiation.

9. Guidant Corporation manufactured and wholesaled medical devices, including the implantable cardioverter biological combination defibrillator (ICD) known as the Ventak Prizm 2DR 1861 Defibrillator which is surgically implanted in the body of patients who are at risk of sudden cardiac death due to abnormal hearth rhythm. A properly functioning ICD detects life-threatening heart rhythm abnormalities and delivers an electrical shock to the heart muscle causing the heart to return to a normal rhythm. Without the electric shock therapy the normal rhythm may not be restored and the patient experiences death. If the device causes inappropriate storm-shocking the heart can be damaged further with the potential of patient death through an induced heart attack.

10. FDA approves medical devices for use in humans and FDA approval was required for the Ventak Prizm 2DR biological combination defibrillator prior to its use.

11. FDA's approval of a medical device for marketing in the United States represents its finding that there is reasonable assurance of the safety and effectiveness of the device for its intended use and conditions of use.

12. On August 27, 2002 James Allen, one of the Plaintiff's directors, was implanted with a 2002 Guidant Combination Biological Model 2DR 1861 defibrillator. According to Guidant, the manufacturer, the defibrillator was manufactured at Guidant's Clomnel Ireland Plant on June 13, 2002.

13. James F. Allen's defibrillator malfunctioned on multiple occasions 2002-2003 shocking the Plaintiff to unconsciousness, down flights of stairs etc.

14. As a result of the malfunctions of James Allen's unit as well as those of other patient's Guidant defibrillators, Guidant's recall of defibrillators other than the Plaintiff's subgroup model, James F. Allen and PFMJ have attempted to investigate the biological combination Ventak Prizm 2DR (1861) devices (approximately 12,926 devices).

15. Part of the investigation involved contacting the FDA to obtain information relating to the Ventak Prizm 2DR 1861 defibrillator to verify the December 2, 2002 statements of Guidant salesman James Davis of Grand Island, NY.

16. James F. Allen and PFMJ made numerous FOIA requests to the FDA in an attempt to obtain information.

17. Plaintiff believes Guidant concealed manufacturing and critical design changes of the Ventak Prizm 2DR 1861 from the FDA, and have placed patients at great risk and endangered their health and lives.

18. Approximately 12,926 Guidant Ventak Prizm 2DR 1861 devices were manufactured April 16, 2002 through November 13, 2002 in this subgroup and never recalled by FDA. Plaintiff believes patients were at serious risk of injury and death. Although Plaintiff believes many patients are deceased there are over 5,000 living that are at increased risk for serious injury and death.

19. James F. Allen and Plaintiff PFMJ have investigated and are dedicated to trying to protect the remaining patients by informing them of the risks of the unrecalled Ventak Prizm 2DR 1861 Combination Biological devices.

20. FDA has records which Plaintiff believes will substantiate the experimental, investigational, non-FDA submitted non-FDA approved, adulterated, misbranded, toxic, and carcinogenic and biological combination devices.

21. James F. Allen telephoned the FDA in 2004 and explained that Guidant employee Richard Roy was misleading the public in stating that repairs had been made on the subgroup of 12,926 Ventak Prizm 2DR 1861 Combination Biological defibrillators and that Richard Roy and his claims about FDA approvals and Guidant Engineering Corrections (eco 44770) for changes made purportedly in 2002 were all fraudulent and misleading at best.

22. Numerous phone conversations ensued over several months but nothing was being researched as requested and Mr. Allen started to realize that his efforts were fruitless even though laws were being broken and patients were suffering injuries or deaths.

23. In 2005 several Guidant Defibrillators were recalled for failure but once again it was stated that Mr. Allen's subgroup was repaired in April 2002 and the devices were in fine shape, not one failure. In the meantime Mr. Allen had been needlessly storm shocked again. In less than 2-1/2 years of a purported 6 to 7 year life span almost 40% of the devices were "no longer in operation". Mr. Allen called Guidant's Daniel Tich and questioned the system of record keeping. His reply

was that the 4,300 patient failed devices discovered by Mr. Allen were removed because the patients wanted to upgrade their devices or possibly get a better cosmetic look with the new thin design. Mr. Allen further challenged Mr. Tich over another group of 600 devices that had been explanted and returned to Guidant by 600 different physicians. Mr. Tich stated the devices were bench tested and they were all fine, nothing wrong with them. In disbelief Mr. Allen pushed no further.

24. About the same time Guidant was praising the subgroup for not having one (1) failure, PFMJ received information through a (PFMJ) FOIA filing from Senator John McCain's staff informing James F. Allen and PFMJ that part of the information the Plaintiff was seeking was on its way from the FDA. The disc showed that two sets of records were being kept - one for the public/physicians and one "confidential" set. FDA public records showed that the Ventak family of devices had experienced 22 deaths 2001-2004. The "confidential" records same period of time, same Ventak family showed 3,834 deaths. Mr. Allen began preparations to have the device removed and replaced with a competitor's device.

25. At about the same time in 2005 Daniel J. Tich, Guidant employee, began a series of written communications with the Plaintiff. .

26. In 2005 the Plaintiff made a last ditch attempt to get the FDA to consider the Plaintiff's accusations on the subgroup of 12,926 devices. Mr. Allen mailed a detailed warning to the FDA and asked that it be printed where the physicians would see the information. After a great deal of pressure on February 7, 2006 the FDA released a **redacted** copy of the warning stating the **"manufacturer was unknown"** and that it was **"Invalid Data" (Report Number - MW1037978) – (MDR - 682033).**

27. Plaintiff continued to follow the various FDA filings available through the FOIA Act, and kept detailed records as the failures in the subgroup continued. By October of 2007 over 9,000 devices had failed.

28. Plaintiff states the Ventak Prizm 2DR 1861 subgroup of 12,926 devices experienced failure that caused serious injuries, additional heart damage, surgeries, pain, suffering and deaths. On information and belief Plaintiff has been told by two Guidant Corporation employees the

following statements about the Plaintiff's original Guidant defibrillator, one (1) of the 12,926 devices ***not*** recalled by the FDA.

a. **February 2, 2004 Mr. Guidant employee Richard Roy** stated:

"examination of the device's header revealed an electrical short... In 2002, guidant became aware that this specific location within the device has the potential to short" "Two months later, ***guidant obtained fda approval*** and ***implemented steps in manufacturing to mitigate this issue (eco 40773)".***

b. **August 19 2005 Guidant employee Daniel J. Tich** stated:

"Specifically you were interested in learning more about ***two corrections actions*** that were taken a April and November 2002... and ***implemented two changes to improve resistance*** to electrical shorting"... "Our first action was a manufacturing change in April 2002." "***A high voltage wire was routed differently*** by manufacturing operators to ensure that it was positioned away from the other electrical components. In addition, operators were asked to verify that an insulative material (medical adhesive) properly surrounded the repositioned wire as a second electrical barrier." "Engineering analysis has subsequently confirmed that these ***April 2002 corrective 'actions' were effective...Although the first corrective action*** was subsequently proven (years later) to be sufficient to prevent future failures of this type, it was also ***decided at the time to make one additional change,*** which was to add another redundant insulation barrier." ***"This change involved designing, acquiring, validating, and gaining approval for an additional component,*** so it was not actually implemented until November 13 2002."

c.**October 12 2005 Guidant employee Daniel J. Tich** stated:

"Your specific device does not include ***a component added to devices starting November of 2002***, which provides redundant protection against the possibility of a short circuit in the lead connection area." "However, no devices manufactured after April 2002, regardless of whether or not they included ***the***

extra component have ever experienced an electrical short circuit in the lead connection area..."

d. **October 27 2005 Guidant Employee Daniel J. Tich stated:**

"Regarding manufacturing changes: ***February changes clarified existing*** manufacturing process steps..." "Nevertheless, as a conservative measure, ***a second, redundant change,*** which as stated in an earlier letter, ***involved designing, acquiring, validating, and gaining approval for an additional component, was implemented in November 2002..." "Be assured Guidant submits changes to FDA officials*** required by internal procedures and law, and has not been **publicly** challenged by the FDA on this topic." "Your device includes the benefit of clarified manufacturing instructions which ensured ***extra care positioning wires in the lead connector*** area so they would remain a sufficient distance from the other electrically actively components." ***"This improved wire positioning also enabled an insulative coating to further protect the device*** from an electrical short circuit." "Today our data indicates that our February actions resolved the issued"

e. **March 7 2006 Guidant Employee Daniel J. Tich** Stated:

"As discussed in a previous letter, ***your device includes one of two improvements*** made to the family to reduce/eliminate the risk of an electrical short circuit." "Your device incorporates manufacturing improvements that significantly reduce the likelihood of the failure mechanism described in our advisory. We knew that operator-dependant fixes are never perfect (as I have explained to you in previous communications) – ***that's why we implanted a final design change later in the year*** ..."

f. **March 15 2006 Guidant employee Daniel J. Tich** Letter states:

"Yes. Medical adhesive coverage was increased in April 2002," "our final corrective action in November 2002 virtually eliminated the human factor relative to this issue ***by adding as extra insulation*** component..." "At the time,

FDA required that minor ***manufacturing process changes*** be filed in an annual report to the FDA (rather than immediately)." "Manufacturing ***changes for this issue were included*** in the next annual report to the FDA, as required."

29. In six ***letters to the Plaintiff they indicated 38 separated times that changes affecting the safety and effectiveness of the Combination Biological Device were made*** and that the Ventak Prizm 2DR 1861 Defibrillator changes were approved. Daniel Tich commented to the fact that the high voltage wire was routed differently and ***two other insulation additions were also made.***

30. Plaintiff's *request* is in reference to the Ventak Prizm 2DR 1861 Combination Biological Adhesive Defibrillators manufactured April 16, 2002 through November 13, 2002, Sub Group approximately (12,926) devices, serial numbers 230796 through 243722. Information and documents relating to the use of a combination biological adhesive and Ventak Prizm 2DR 1861 defibrillator.

31. Upon information and belief the Plaintiff and Guidant recognized without question that the changes that were made affected the **safety and effectiveness** of the devices and that the change in adhesive caused the failures. All of these changes were made and devices sold and implanted ***prior to any FDA supplemental PMA submission or approvals*** of the header connector repairs. Evidence strongly states that there was no FDA supplemental submission or approvals for the brand new "Combination" Biological Devices (12,926 units).

32. Plaintiff has researched all FDA files available to the public January 2001- December 2002 including PMA's; Supplemental PMA's; IND's; NDA'S; ANDA's and the Guidant's purported ECO 40773 changes. Guidant did **not file or obtain** FDA supplemental approvals for the two (2); Class III Investigational devices manufactured into a "Combination" biological/device April 16, 2002 through November 13, 2002 (12,926) units.

33. [21 CFR 5.701]; [Section 301] introducing a misbranded biological combination device into commerce. Labeling failed to bear adequate directions for each intended use. [Section 502] the Combination biological device was misbranded, and its labeling was false and misleading. Upon information and belief including Guidant Corporation employee statements experiments took place with several different Biological Adhesives in combination with the Ventak Prizm 2DR 1861

Defibrillator Sub Group 2001 through 2002 without FDA notification, supervision, submission or approval.

34. [21 CFR 201.128] "intended use" Upon information and belief Guidant employee statements and Plaintiff's research, Guidant Corporation used one of several adhesives, *untested, unapproved and non FDA submitted,* including but not limited to **Nusil Liquid Silicone Rubber MED-4870; Rehau Raumed Polyethylene Terephthalate Silicone Glue 1511** and on Plaintiff's information and belief **Dermabond High Viscosity Line Extension Adhesive;**

a. On February 11, 2008 the FDA stated that Guidant's approval (P010012/S167) was **for "replacement" of the "current" Rehau SI-1511 medical adhesive...."** (FDA PMA, Supplemental PMA, records 2001 through February 11, 2008 show no submissions or supplemental submissions to have experimented with or used the Rehau SI 1115 for the Header Connector Topping and as a bonding between the titanium can and the header itself. There are no (0) FDA filings for Rehau SI 1511 January 1 2001 through December 31, 2002. Therefore, the known use **was without FDA submission or approval, an "OFF LABELED Combination Biological Device."**

b. Once again FDA records 2001-2002 show **no FDA filings or FDA approvals** for the use of either the **Nusil Liquid Silicone Rubber MED-4870, Rehau Raumed Polyethylene Terephthalate Silicone Glue 1511 or any other adhesive changes.** The above February 11, 2008 filing is the first time Guidant filed with the FDA regarding the use off labeled, adulterated, misbranded, non FDA submitted, non FDA approved adhesives used in Combination non FDA approved, and non FDA supervised human clinical trial without patient consent or knowledge.

35. [Section 505(a)] on information and belief, Guidant, in violation, introduced the **new biological combination investigational devices** into commerce without an approved application. [Section 505(d)] the **new biological combination investigational devices** had ***not*** been shown to be **safe and effective or reasonable and necessary** under the conditions prescribed, recommended and suggested in the labeling. [Kordel v. Unites States, 335 U.S. 345 (1948)].

36. The two (2) investigational devices placed in combination required Cross-Labeling and Reciprocal approval by the FDA because they became **two Investigational Class III Medical**

Devices manufactured into one Biological Combination Class III investigational Device. Guidant "established a commercial market and intended use for the investigational biological combination device for unapproved sales and off labeled therapeutic uses."

37. Guidant may neither label nor promote the combination for use with the biological and unapproved investigational devices nor may Guidant package the investigational biological devices with the Ventak Prizm 2DR 1861 prior to FDA having approved the combination. **There was no 510(k)'s, Supplemental PMA's or NDA's in existence for the unapproved investigational two Class III device combination. (This Combination Biological Ventak Prizm 2DR 1861 was *NOT a FDA cleared device.)***

38. The key points of statutory interpretation, in this case [Section 503 (g)] ***there was no FDA submission for the combination biological device*** which prevented the FDA from using any agency resources to ensure adequate review of the safety, effectiveness, reasonableness or necessity of the two Class III investigational devices in combination. Section 503 (g) is more than jurisdictional. *combination products are in a special separate class [See Section 563]* recognizing stand-alone category of "combination medical devices".

39. Section 201 (g)(1) and Section 201 (h) "drug" definition amended in 1990 to eliminate "device" exclusion. The use of these two Class III medical devices- the Ventak Prizm 2DR 1861 Defibrillator and one (1) of several Class III Biological Adhesives experimented with without FDA approval, supervision, or submission, were ***not*** **novel uses of cleared devices. Neither of these devices was cleared for any novel uses under Section 201 (h). These devices were *NOT components, but investigational, experimental Class III medical devices, requiring full and supplemental PMA approvals. Example June 13, 2002, the Guidant manufacturing date of the Plaintiff's personal combination failed device, Serial number 233403, and combination device.***

40. [See 21 CFR 3.2 (e)] these two devices were ***product specific*** and triggered the statutory requirements of full supplemental PMA approval and labeling for the combination. **Guidant created a new intended use in manufacturing the combination of any of the biological investigational adhesives used with the Ventak Prizm 2DR 1861 defibrillators.**

41. **FDA regulation of Combination Class III Medical Devices (November 25, 2002).**

a. Sections 563 and 503 (g) as amended, clearly recognize "Combinations", any Biological product and Defibrillator device, as a stand-***alone*** category.

b. Statue (503 (g) (1) constitutes a **combination** of a Class III biologic and device.

c. A combination exists when two or more articles are physically or chemically combined, packaged together or intended to be used together.

d. This combination is identified as separately regulated parts within the whole of the combination biological defibrillator.

e. This combination was and is without all necessary data, as there was no Supplemental PMA, NDA, or BLAs submitted.

f. **"Lack of Transparency"** On information and belief lack of transparency included no decisional documents in summary approval materials; no "Annex" to next generation ICA product; no precedents were available to the FDA staff; no classification or assignment decision were with a written record of decision and no standards for mixed or hybrid regulation were set forth in a rule.

g. The two Class III devices meet both the definition of a biological and device. Therefore the FDA was ***not*** given the discretion in determining how to treat them...

h. **Conclusion:** What the FDA has never done and, in the Plaintiff's opinion, will never do, is to treat two Class III investigational experimental devices dissimilarly and permit two sets of similar products to run down two separate tracts, one more treacherous than the other **for no apparent reason.** CF Bracco Diagnostics, Inc. v. Shalala, 963 F. Supp. 20, 28, (D.D.C. 1997) **(when the decision did not relate to approval of the device, jurisdiction is in district court.) (There were no FDA submissions or FDA Supplemental submissions or approval letters for the new device combination from the FDA.**

i. The device at issue in this case fits in the statutory scheme. Congress has charged with determining the issue, that is whether this particular combination biological device has been

submitted or approved and in effect whether it was reviewed by FDA using the appropriate regulatory pathway [21 U.S.C. 360c-360k.]. **In this case the FDA could only have relied on scientific expertise,** determining the proper regulatory pathway for these two Class III medical devices **in combination. (There was no Scientific Expertise provided by Guidant this was a brand new Class III device ("Never Submitted") regardless of which investigational adhesive was used.**

j. [FDA 21 CFR 5.10 (a) (1)] (Class III devices); before marketing [21 U.S.C. 360 c (a) (1) (C)]; FDCA to receive PMA Supplemental approval or qualify for exemption [360e] for experiments from PMA approval, **manufacturer must submit an application containing full reports of investigations that provide "reasonable assurance" of the safety and effectiveness – reliability and necessary** of the combination device.

k. **This device "combination" regardless of which adhesive** was used, including *Raumed Polyethylene Terephthalate Silicone Glue SI 1511 – Dermabond High Viscosity Line Extension or Liquid Silicone Rubber MED-4870 and others the product combination* **(1) was never marketed before, and was never submitted for FDA decisions [360e (b)(1)(A)]. (2) There was no supplemental PMA, 510(k), IDE and the combination was not "substantially equivalent" to any other devices, as the combination was without FDA PMA or supplemental PMA approvals. Guidant changed the design in a manner that affected its *safety and effectiveness*, without a supplemental PMA application causing failures, injuries and deaths in the combination devices. [360e (d) (6) (A)]; and [360 (d) (6) (B)].**

l. Guidant decided to make "changes" according to their employees Richard Roy and Daniel J. Tich. These were major changes affecting the safety and effectiveness. The combination biological device required a full FDA PMA, or supplemental PMA filing and approval. Those changes rendered the combination device no longer non exempt and therefore they were non marketable products [360c (f)]; [360c (a)]. The changes to the combination devices were without 510(k) or the PMA processing. **These "Combination Biological Defibrillators with the unapproved experimental biological adhesive had never been on the market and required Supplemental PMA's or full PMA's. The brand new combination was not submitted for approval.**

m. The addition of the new features (adhesive changes) triggered the requirement that the new combination biological device obtain a supplemental PMA or full PMA **approval.** Whichever experimental adhesive was added, it caused the device to become a combination biological brand new device. It was a change sufficient that it was no longer the same device. The device changes put the device on a different regulatory pathway. There can be (no) question the changes were made **prior to any approvals. There was neither a 510(k), supplemental PMA nor full PMA approval for the Model Ventak Prizm 2DR 1861 Combination Biological Device.**

n. There is no issue of fact that the supplemental PMA or full PMA approval was non existent prior to the changes made without FDA submission. There is no issue of fact that FDA never approved the new biological combination device. It was never submitted to the FDA. **The law on whether a PMA approval may apply to a combination biological device is clear. To approve a PMA Combination Biological Device the FDA must find that there is a "reasonable assurance of safety and effectiveness" of the device as it is described in the application.**

o. **The changes effecting the safety and effectiveness of this device were made prior to any supplemental approvals April or November 2002 and were never FDA "Submitted." [21 U.S.C. 360c (a) (1) (C)]. Every PMA must meet this legal standard to be approved, the law allows no exceptions.** Furthermore, it is the whole combination device as it is described in the application that must meet this legal standard for approved PMA. **The law simply does not allow** a "Combination Biological Device, two (2) Investigational, Experimental Class III medical devices **to be placed in combination forming one entity and not be FDA submitted for approval.**

p. The FDA determines the scope of a brand new biological combination defibrillator, two Class III medical devices combined and the appropriate regulatory pathway for the single investigational combination device. **However, only when the combination device is submitted by the manufacturer for Supplemental Approval or PMA approval and *only when the FDA knows the brand new devices exist, can the FDA approve the application.* In this case not only did the FDA not know the combination device existed, the FDA had no idea a non FDA approved, non FDA supervised, investigational human experiment was taking place using Liquid Silicone Rubber**

MED-4870, Raumed Polyethylene Terephthalate Silicone Glue SI 1511 and other non FDA approved biological adhesives in the various experiments. (No FDA Filings.)

q. The materials and changes were *not* submitted to the FDA **for supplemental PMA approvals and were, in fact, two new investigational, experimental biological devices placed in combination - a brand new Class III biological medical device** requiring a PMA Application.

r. THIS WAS NOT A MODIFICATION OF AN APPROVED DEVICE OR EQULIVANT DEVICE. THIS WAS A BRAND NEW COMBINATION OF TWO NON-FDA APPROVED CLASS III MEDICAL DEVICES PLACED IN COMBINATION.

s. **In no way was this device labeling identical to the labeling approved in the draft form. The changes were not identical or explained in any amendment,** including rerouting the High Voltage wire and the change in insulation and medical adhesive, including the experimental adhesives used 2001 through 2002, without FDA approvals, Liquid **Silicone Rubber MED – 4870,** Raumed Polyethylene Terephthalate **Silicone Glue SI 1511 and on information and belief, others.**

t. The changes made in the Ventak Prizm 2DR 1861 Combination Biological device caused the device to be in combination with another Class III medical device therefore forming a **"Combination Experimental Investigational Biological Device."**

41. Upon information and belief it is the Plaintiff's understanding that Guidant Corporation representatives stated 2001 and 2002 they had experimented with Silicone medical adhesive, Rehau SI 1511; Nusil Med 4870 Part B and other experimental combination adhesives and chose one of the new biological adhesives in formulating the Class III biological combination Ventak Prizm 2DR 1861 Defibrillators, manufactured April 16, 2002- November 13, 2002. FDA records 2001-2002 show no "Combination Biological Device" FDA filing for a **new** medical adhesive to be used in combination in the header connector cavity or inside the titanium can wall and plastic header casing of Guidant's (12,926) subgroup of devices.

42. FDA records available show no combination device FDA filings, therefore Plaintiff's belief is that none of these **adhesive experiments** had FDA approval or FDA supervision and as a direct result of arbitrarily picking an adhesive they caused a long term effect inside the human body of premature rapid disintegration and device failure. If Guidant was using any of these adhesives it was being done in a non FDA approved, non FDA supervised, human clinical trial without patient's consent or knowledge (12,926) devices (Serial Number 230796 through 243722).

43. Plaintiffs did discover that in 2001 through 2002 Guidant in their 10(k) Securities Exchange Commission filing to the stock holders had stated in part the following.

a. "The Company purchases certain supplies from single sources due to quality considerations, costs **or constraints resulting from regulatory requirements**". "The Company cannot quickly establish additional or replacement suppliers for certain components or materials, **largely due to the FDA approval system...."** "suppliers have announced that, in an effort to reduce potential product liability exposure, they intend to limit or terminate sales to the medical technology."

b. **"The Company has agreed to indemnify certain suppliers** against potential product liability exposure and **the Biomaterials Access Assurance Act of 1998...."**

44. Biomaterials Access Act of 1998 states in part: (LSU Law Center 1999)

a. "Last year Congress passed legislation protecting suppliers of bulk components and raw materials for implants from lawsuits." "The BAAA applies to all implant raw materials and components **except the silicone gel...."**

45. **Guidant was *identifying* a new Silicone adhesive manufacturer, in it indemnification.**

46. **The only FDA Guidant approved adhesive in the United States** for internal body use in combination defibrillators 2001 through 2002 **was the Tecothane 1075 D-M Polyurethane PMA # 89006/S011,** as a header connector topper material for all defibrillator manufactures including Medtronic and St Jude the first and third largest producers of defibrillators in 2001 through 2002.

47. (May 1995 Blue Book) Medical Device & Diagnostic Industry (MD&DI) states in part:

a. "...Tripartite Guidance would be replaced with ISO 10993 as the criterion for evaluating the safety of materials used in medical devices." "The biological evaluation should be planned and **carried out by knowledgeable and experienced individuals** capable of making informed decisions based on the advantages and disadvantages of the various materials and test procedures available."

b. "Materials such as silicone undergo quality testing to measure tensile properties, elongation and modulus."

48. **FDA Biologic Master Files** (MAFs) were developed by the FDA; the purpose of the files is to protect Data under trade secret on Biological Adhesives and other materials located at Centers for Biologics Evaluation and Research Document FDA Control Center, 1401 Rockville, MD 20852-1448.

a. Often the **applicant of SPMA's; PMA's; IDE's; 510 (k)'s; filing for 'combination biological devices** requires the 3rd party information of adhesive manufacture's like Nusil Technology; Liquid Silicone Rubber MED-4870 or Rehau Inc. Raumed Polyethylene Terephthalate Silicone Glue SI 1511 or other manufactures such as Closure Medical Corporation, Dermabond High Viscosity, **in completing *a required* FDA submission and FDA filing for approval to market the new combination biological devices.**

b. The purpose of making the information available is that these adhesives are for the most part raw materials and not sterilized, therefore when manufactured into Class III medical biological combination devices, creating a new device, **the combination must be FDA** *approved for internal body use,* as in this case. Therefore sound scientific evaluation must be made for the new combination biological device, the review of data and other information related to the other party's adhesive, facility, and manufacturing procedures is FDA required.

c. Information supplied may be, notice of claimed investigational exemption for new drug (IND filing) for biological and biologic licenses or data supporting Investigational new drug applications (IND's), (NDAs) filings.

d. These MAF's are accepted by the FDA from companies who will not submit the information in a PMA, IDE, and 510(k). As a result of the above procedures on the adhesives, a;

> "client's" (Guidant) "submission maybe adversely; affected if the MAF is incomplete or inaccurate." " This is especially true in the case of a PMA because of the statutory requirement that a PMA contain a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of the device."

e. (Adhesives Status 2001-2002) MAF MED-4870 adhesive, was ***"off labeled", no FDA approval*** for combination biological device. Rehau SI-1511 Medical Adhesive was **experimented with by Guidant with *no FDA approval.*** On information and belief DERMABOND was also **experimented with by Guidant with *no FDA Approval.***

f. **Which adhesive was finally used is unimportant** because there were no 510(k) s, IDEs, PMAs, SPMAs, INDs, or NDAs, FDA filed 2001-2002 for the "Combination Biological Class III Medical Device" which **was brought to market without an FDA Submission.**

g. The 12,926 devices were experimental and investigation **non FDA submitted / non FDA approved** Class III Combination Biological Devices.

FOIA REQUESTS FAILURES

49. Plaintiff has repeatedly made FOIA *requests* to obtain information from the FDA through the entire investigation, but has been totally been without success.

50. The following will explain the final attempted the Plaintiff's put forward at acquiring the various information known to be held by the FDA.

51.On February 21 and 22, 2008 in a letter addressed to defendant FDA, attention Mr. Fred Sadler, Director of the Division of Freedom of Information, Plaintiff requested copies of all

information submitted in the approved processes of several changes Guidant and Closure Medical Corporation had made.

52. FDA's Fred Sadler's response was to send only public records without details of the changes requested. Plaintiff has the public records.

53. On December 3, 2008 Plaintiff made another FOIA request to Defendant by letter addressed to FDA, Division of Freedom of Information, and Attention Claire B. Brodsky with copies to the Office of Combination Products (HFG)-3 Food and Drug Administration, 15800 Crabbs Branch Way, Suite 200, Rockville, MD. 200855, Dr. Joseph Milone, Ph.D., Biologics/Office of Combination Products and Suzanne M. O'Shea, 600 East 96th Street Suite 600 (CBER), Indianapolis, Indiana 46240, Regulatory Requirements (IRB) Biologic/Office of Combination Products..

54. In the December 3, 2008 letter, Plaintiff made the following revised requests:

"Revised Request:"

("a") The FDA ["will provide us with copied documents,"] that show that Guidant's Ventak Prizm 2DR 1861 Defibrillator was a "Combination", FDA (PMA) filed and approved device, with Closure Medical Corporation's DERMABOND High Viscosity Line Extension "Topical Skin Adhesive" under 21 CFR 3.2 (e)(1); Subparts (A); [Center for Biologic Evaluation and Research]; and on or about the "Third Quarter" of 2001 through November 13 2002 the two devices were filed as FDA "Combination Device" [Definition:] "A single product comprised of two or more "regulated components". In this case, "Unapproved Medical Adhesive and Unapproved Implantable Defibrillator."

["Or"] If Request (a) cannot be fulfilled we ask that the FDA provide Request (b)

"Revised Request:" ("b") The ["FDA will complete the request by providing a letter"] from a FDA officer, with a complete statement (information) that the Guidant Corporation and Closure Medical Corporation, DERMABOND High Viscosity Line Extension "Topical Skin Adhesive and the Ventak Prizm 2DR 1861 Defibrillators **were**

> **not and are not filed or approved as a "Combination Device"** and that the definition of a "Combination Device" under Subpart B (3.2)(e)(1); [CBER], is "a product comprised of two or more regulated components" (i.e. biologic/device components), that are physically or chemically "Combined", "Mixed" and produced as a ("Single Entity")
>
> Finally a statement that neither Ventak Prizm 2DR 1861 Defibrillator nor Dermabond High Viscosity Line Extension "Topical Skin Adhesive" was FDA (PMA) approved the "Third Quarter" of 2001.

55. Prior to January 25 2009, plaintiff made a FOIA request from defendant for records regarding "Guidant Corp. – Combination Biologic/Device PMA (or Supplemental PMA) for 7/1/01-11/13-02".

56. On January 28, 2009 FDA by letter from Claire B. Brodsky, Information Technician, acknowledges Plaintiff's request and stated that "We will respond as soon as possible."

57. On January 25, 2009, Plaintiff made another FOIA request to Defendant by letter addressed to FDA's Division of Freedom of Information Attention: Fred J. Sadler (Chief Information Officer) and FOI Technicians. Plaintiff requested the following:

> 1. Copies of PMA or Supplemental PMA filing with the FDA for "Combination" Biologic/Device from Guidant Corporation. The device filing would include Guidant's Ventak Prizm 2DR 1861 Model and Closure Medical Corporation's DERMABOND High Viscosity Line Extension "Topical Skin Adhesive" shipped the third quarter of 2001 to Guidant Corporation (Ireland) for injection into the April 16, 2002 through November 13, 2002 (12,926) unapproved devices.
>
> 2. A copy of the filing by Closure Medical Corporation and/or Ethicon, Inc. for the third quarter of 2001 shipment of the DERMABOND High Viscosity Line Extension "Topical Skin Adhesive" to Clomnel Ireland.

58. On February 4, 2009 by letter addressed to FDA's Division of Freedom of Information, Attention: Claire B. Brodsky and Veronica Graves for the second time Plaintiff requested the FDA

advice in writing. Was or was not the agency (FDA) provided an Application for a (Non-FDA recalled) "Combination" Investigational Biologic/Device "submitted" 2001-2002 from Guidant Corporation, a [21 CFR 3.2 (c)] PMA or Supplemental PMA?

59. On February 9, 2009 by letter addressed to FDA's Division of Freedom of Information, Attention: Chief Counsel Deputy Joy Lazaroff, plaintiff requested the FDA to confirm in writing the following: Did the Guidant Corporation submit a "Combination Biologic/Device" the third quarter of 2001 through November 13 2002 (yes) or (No)?

60. By letter dated February 18, 2009, FDA's LCDR Lisa D. Lawrence from FDA's Freedom of Information Branch responded to request F2008-1597 that the FDA did not find the requested records and that FDA/Center for Devices and Radiological Health does not have Premarket Approval Applications (PMA) that is specific to the combination products or devices described in your request.

61. By letter February 19, 2009. FDA's W. James Gardner, Chief, Consumer Affairs Branch, Division of Communication and Consumer Affairs, Office of Communications, Outreach and development, Center for Biologics Evaluation and Research that:

> We have reviewed the background information you supplied concerning your Freedom of Information Act request to the Center of Devices and Radiological Health (CDRH). We understand one's frustration when they do not get the answers they are seeking. We have contacted CDRH, and please are assured that they are fully aware of your request and concerns. You will be contacted by CDRH directly if there is any additional information they can provide.

62. There has been no response from CDRH.

63. On February 24, 2009 by letter Plaintiff made a FOIA final appeal to FDA Division of Freedom of Information, Attention: Clara B. Brodsky. Plaintiff's appeal letter was in reference to Plaintiff's request as set forth in Plaintiff's December 3, 2008 and February 2009 FOIA letter requests.

64. By letter dated March 5, 2009, Department of Health & Human Services, Director of FOIA Services, Carol Maloney wrote:

> This is in response to your September 10, 2008 Freedom of Information Act (FOIA) request for records pertaining to the Closure Medical Corporation brand new Dermabond High Viscosity Topical Skin Adhesive line Extension Adhesive (HVD).

65. Ms. Maloney stated the FDA may have records responsive to the request and advised that the request was referred on October 15, 2008 FDA (Case No. 2008-7536) to Fred Sadler Freedom of Information Officer.

66. On March 2, 2009 Plaintiff made another FOIA request to FDA by letter addressed to LDCR Lisa D. Lawrence. This letter followed up Plaintiff's previous request and replied to Ms. Lawrence's February 18, 2009 letter. The March 2, 2009 letter stated it was a Second/Final FOIA Request.

67. The Plaintiff has repeatedly over a full year+ of attempts, narrowed and reduced the FOIA requests all to no avail.

FACTS

68. These devices manufactured April 16, 2002 through November 13, 2002, approximately 12,926 units, serial numbers 230796 through 243722 were brand new, **non FDA submitted,** experimental, investigational, **"Combination Biological Defibrillators".** Years 2001 through November 13 2002, Guidant Corporation's Daniel J. Tich, Richard Roy, and other Guidant employees have either "stated in writing" or "admitted verbally" or "both" that **changes and additions were made** to these devices.

69. Investigational and experimental **Changes and Additions** were made that affected the "safety and effectiveness" causing the devices not to be "reasonable and necessary" and Guidant moved those devices into interstate commerce without a 510(k); Supplemental PMA; or PMA approvals. **A Brand New Combination Biological Device without human clinical trials.**

70. Richard Roy in 2004 stated to the Plaintiff that an Engineering Correction Order (ECO 40773) was implemented into the device to correct a shorting defect and that Guidant obtained FDA approval. **Both were fraudulent statements.**

71. In 2005 Daniel J Tich stated to the Plaintiff that **changes and additions were made in the adhesive.**

72. Other Guidant employees have admitted in writing and verbally that adhesives including NuSil Liquid Silicone Rubber MED-4870; Rehau Silicone SI 1511; and "others" were being **experimented with** 2001 through 2002 inside the Ventak Prizm 2DR 1861 Combination Biological devices.

73. Not one of these experimental/investigational adhesives **known to have been changed** were ***FDA submitted or approved*** for the Brand New Combination Biological Ventak Prizm 2DR 1861 Defibrillator, **two Class III, biological, investigational, experimental medical devices** placed in combination **without FDA filing.**

74. On **December 18, 2007** Guidant Corporation admitted to the FDA that the Company had been using Rehau SI 1511 medical adhesive and **requested a change in adhesive** to a new Med – 1515 adhesive. From January 1, 2001 through December 18, 2007 Guidant did not file for any experimental use of the Rehau SI 1511 adhesive **as a header connector cavity insulation topping or header bonding glue to the inside titanium can** of the Ventak Prizm 2DR 1861.

75. Therefore, various Guidant **employee's statements of using Rehau SI 1511 Adhesive inside the defibrillator and experimenting** to repair the shorting defect shows that **Guidant employees were using Rehau SI "Off Labeled"** and created an ***unapproved "Off Labeled" Promotion.*** Guidant was prohibited from promoting the Ventak Prizm 2DR Combination Biological Device regardless of the brand of ***adhesive that was "changed".***

76. GUIDANT WAS PROHIBITED from omitting risk; overstating effectiveness; making unsubstantiated claims of the ***off label device use*** that failed; the use and promotion was inherently fraudulent; the premature failures contest to the ineffectiveness and lack of safety; the devices were ineffective and dangerous for the off label uses for which they were purchased; not one patient or physician would have used the device in the unapproved off labeled condition; the 12,926 devices

were ineffective in all populations; all of these devices implanted were inadequate and inferior, with severe patient injuries and deaths as the devices failed; on December 2 2002 the Plaintiff was being told by Dr. Jeanne Basior the devices were incorrectly reading normal SVT's for Deadly VT causing needless storm shocking and additional heart damage.

77. Starting July 18, 2002 every device sold from the subgroup was **"off labeled"** *regardless of which changed biological adhesive was used in combination* with the Ventak Prizm 2DR 1861 devices. The FDA was not notified and no FDA applications were made for the new "Combination Biological Device". The plaintiff has specifically alleged 6 submissions of false and fraudulent sales and implantations of the combination biological devices. Guidant was promoting a non FDA approved ***"off labeled"*** use.

78. Furthermore, federal healthcare programs including Medicare, Medicaid and the Veterans Healthcare Program do not knowingly pay for Class III investigational medical devices that are prescribed for fraudulent indications. One Hundred percent (100%) of the subgroup 12,926 devices were implanted ***off labeled,*** their use not being medically indicated or necessary the claims were not eligible for federal financial participation or covered by state Medicaid programs. (id., 239, 241). Medicare or the Veterans Administration is billed only for costs permitted. These devices were implanted in an unqualified trial and were not reasonable and necessary items used to diagnose and treat complications arising from participation in a non FDA approved clinical trial.

79. **No patient or insurer can bill for investigational medical devices unless the FDA has issued an investigational device exemption (IDE);** without the FDA's prior written approval, in this case for a Combination Biological Device, there can be no VA, Medicare/Medicaid reimbursements. When there is an IDE or when the FDA gives prior approval, charges to subjects must be described **in a written consent document;** in this case **there was no consent or knowledge of the experiment provided.** The costs for the devices that were experimental are not considered medically necessary, safe and effective and may not be billed to the VA, CMS or Medicaid. The sponsor (Guidant) of the unauthorized, non FDA approved clinical trial is totally responsible for the funding of the devices, procedures and care of the patient costs, device removal and replacements.

80. These devices manufactured April 16, 2002 through November 13, 2002 were ***non FDA submitted, "off labeled", n***on FDA approved, investigational, adulterated, misbranded,

"Combination Biological Experimental Devices", ***fraudulently certified for federal dollar reimbursement.***

81. According to Guidant employees Rehau SI 1511 was one of the adhesives used with the Ventak Prizm 2DR 1861 Combination Biological Defibrillator experiments. **If this statement is true,** Guidant used the Rehau SI 1511 **off labeled, investigational, and experimental, without FDA submission or FDA approval.**

82. **You can *not* change the use of the Rehau SI 1511 adhesive from an approved use, to a non approved use.** Regardless of which experimental adhesive was illegally used by Guidant, ABC, XYZ, or REHAU SI 1511, Guidant did not file with the FDA for a ***change in adhesive*** or a ***change in the use of any adhesive.***

83. **"Off label" and investigational Use** of a Biological Adhesive Class III **marketed** Medical Device. The investigational use of an approved, marketed biological adhesive, in context of a clinical protocol [see 21 CFR 312.3 (b)]. When the principal intent of the investigational use of a **test article is to develop information about the product's safety or efficacy,** submission of an IND or IDE is required. Guidant provided nothing but Guidant employees have stated they were experimenting.

a. According to 21 CFR 312.2(b)(1) the clinical investigation of a **marketed** biological adhesive, for (Example **Raumedic SI 1511)** ***DOES*** **require submission** of an investigation New Device Application ("IND") if **any one (1)** of the following conditions **are not met. Example:**

*b. **NONE OF THE CONDITIONS WERE MET BY RAUMEDIC SI 1511 ADHESIVE OR ANY OTHER ADHESIVE IN COMBINATION.)***

(i) The Raumedic SI 1511 **was NOT intended to be reported** to the FDA in support of a new indication for use or to support any other significant change in the labeling for the biological adhesive. **(Example** an ***"Off Labeled use"*** of the **Raumedic SI 1511,** as a Header Connector Topping or Header Titanium Can Bonding;

(ii) it would support a significant **change** in the advertising for the product;

(iii) it would involve a route of administration or dosage level use in a subject population or other factors that significantly increase the risks and decreased the acceptability of the risks associated with the adhesive. **For an example, if one was to replace the FDA approved Tecothane TT1075D-M Polyurethane Header Connector Topping and bonding adhesive with the Raumedic SI 1511 adhesive product;**

(iv) if it was ***not*** **conducted** in compliance with Federal requirements for IRB review and information consent [21 CFR parts 56] and [50], Protection of Human subjects respectively];

(v) if it was ***not*** **conducted** in compliance with requirements concerning the promotion and sale of the brand new adhesive [21 CFR 312.7;], Investigational New Biological Adhesive Application and

(vi) if it was ***not*** **intended** to invoke [21 CFR 50.24]. **Exception from informed consent requirements for emergency research.**

PFMJ's REQUEST FOR EXPEDITED PROCESSING

84. With respect to this request for expedited processing pursuant to 5 U.S.C. 552 (a) (6) (E) (v) (ii) Plaintiff Patients For Medical Justice Ltd. (PFMJ) has been involved in the exposure of fraud, injuries, and deaths from the known non FDA submitted, non FDA approved, Combination Biological device along with the dissemination of information to the public as referred to in [31 CFR 1.5 (e) (2) (ii)]. As to the urgency of the requests (PFMJ) states the following:

85. PFMJ's requests concerns matter of exigent and current interest to the American Public. Specifically, the American public has a compelling need to be immediately and fully informed about the sale of "off labeled" investigational, experimental, non FDA submitted, non FDA approved, life sustaining "Combination Biological Devices sold and implanted adulterated, and misbranded.

86. The Combination-off labeled-biological-devices were delivered to market, interstate commerce, as a direct result of an understaffed, under paid, over worked FDA and FDA officials. To date whether intentional or not The FDA has been furthering the fraudulent cover-up and scheme. Entities have been charged with but understaffed for the responsibility to let none of this type of behavior to occur let along flourish.

87. Public confidence in the institutions of government and its private surrogates is important to the stability of and recovery of an already severely damaged health care system. Access to the requested information in full without redaction other than names, in PFMJ's opinion, is imperative to the public's confidence. As the Plaintiff is one (1) of the 12,926 victims of the criminal experiment and has experienced the additional heart and nerve damage, additional surgery, hospitalizations, along with loss of control of arms and hands, the Plaintiff can personally attest that sunlight is the only disinfectant to bring this lack of accountability and transparency to the attention of the American public.

88. In 2005, 4,300 of the devices had failed. By October 2007 the count had reached approximately 9,000 plus. Any further delays on the part of the FDA in the release of this FOIA requested information is further endangering the lives of the remaining victims of the off labeled devices, without the benefit of consulting with their physicians as to what courses may be best for them. In addition, any further delay would disrupt the public's ability to make its views known to public officials just as those officials are daily being asked to make critical and sweeping decisions based on limited information of the FDA's efforts. Significantly, any further delay will further undermine public confidence in the integrity and reliability of the FDA, further eroding the American financial system.

89. With respect to the FDA not granting the information and expedited processing the Plaintiff can no longer allow the critical need for the complete information to be disregarded pursuant 5 U.S.C. 552 (a)(6)(E)(ii)(I).

89. As of the date of this filing the FDA has not responded to PFMJ's FOIA applications for expedited 20 business day processing other then informing the Plaintiff that "no records found" or the "records do not exist". The information the Plaintiff is requesting **does exist in the IDA, PMA, Supplemental PMA files in one form or another or the FDA can provide a written statement as to if a FDA required filing was completed.** The Plaintiff has narrowed the request

and the remaining 5,000 patients need to be informed so they can avoid additional pain and suffering and get their units replaced...

90. The Plaintiff's will no longer allow the FDA to ignore our request at the expense **of non consenting, unknowing 65 year old patients** being use in a non FDA approved human clinical trial experiment.

91. As these acts continue including non FDA submitted devices, non FDA approved Combination Biological devices, non FDA supervised human clinical experiments, fraudulent reports, fraudulent off label uses, fraudulent off labeled devices, Guidant continued to experiment with several investigational Biological adhesives and upon **information and belief and Guidant employee statements, written and verbal,** experimental, off labeled, investigational use took place with but was not limited to;

Dermabond High and Low Viscosity Line Extension Adhesive **(Not FDA Approved);**

Nusil Med 4870 Adhesive, **(Used Off Labeled); (Not for It's Intended Use);**

and Rehau SI 1511 Adhesive **(also Not FDA Approved).**

Combination Biological Ventak Prizm 2DR 1861 Device **(Not FDA Approved) and used ("Off Labeled").**

92. All uses and changes made were criminal acts. Changes that caused the devices to reach interstate commerce without a 510 (k), (PMA) (Supplemental PMA) and were **"Off Labeled",** causing the SAFETY AND EFFECTIVENESS of the Ventak Prizm 2DR 1861 Combination Biological Devices to fail.

93. In a letter dated April 7, 2009 FDA's LCDR Lisa D. Lawrence from FDA Freedom of Information Branch responded to Plaintiff's September 10, 2008 letter regarding reference numbers 2008-6665, 2008-6747 and 2007-7536. Ms. Lawrence advised that the FDA "will respond as soon as possible for a redacted copy of P960052 Supplement for design, and components/specifications" and claimed an exemption in reference to shipment records of Dermabond to Ireland and to letters and documents from Ireland since FDA does not have regulatory authority over devices approved

for distribution in Ireland, ***this may be true.*** However, the adhesive was without CE Mark, for class III Investigational non-FDA approved adhesive shipped from the U.S. and injected into defibrillators. Experimental adhesive **of any brand** imported from any foreign country, including Clomnel Ireland into the U.S., the FDA does have regulatory authority to require submission of documents verifying the Non FDA Approved High Viscosity Line Extension Dermabond or any other experimental adhesive was ***not*** interring the U.S., and on information and belief, these Combination Biological Devices were entering the U.S. without FDA approval, had been "barred" from the U.S. and "banned" from internal body use. Ethicon Inc. the shipper must maintain the records of who in Clomnel Ireland purchased $4,873,000 million dollars of DERMABOND (HVD) August 9 2001 (Investigational Device) and $117,000,000 Million dollars August 9 2001 through May 23 2005, from Closure Medical Corporation. Guidant must have records of what devices received the Non FDA approved ***adhesives.*** Guidant employees have already admitted that ***various experimental adhesives were use. Guidant payments (checks) will show what adhesive was used.***

94. Not only was Lisa D. Lawrence's response incomplete as to Plaintiff's September 10, 2008 request but Ms. Lawrence's letter failed to address or respond to Plaintiff's March 2, 2009 FOIA request.

95. Plaintiff, in its repeated FOIA requests as set forth and in its letters has met the criteria for expedited processing under FDA's regulations. Plaintiff stated the information was urgently required to inform the public and 5,000 patients.

96. Plaintiff's requests for documents and information are within FDA records and ability to ferret out. Plaintiff started warning the FDA in 2004 and then again in February 2006 in writing with regards to the use and failures of the off labeled device, non FDA approved and off labeled uses of the various experimental adhesives, Guidant employees have admitted they were used, in non FDA approved changes, including Nusil Med 4870, Rehau SI 1511 and upon information and belief DERMABOND High Viscosity. (All of the adhesives were criminally used on the 12,926 sub group of combination devices and one was chosen over the others after the experiments.

97. FDA's limited response that the information is non-existent raises questions about the government's integrity which affects public confidence.

98. Plaintiff believes that without the legal and statutory correct requested information, thousands of remaining patients who have the non FDA approved devices implanted are at serious risk.

99. FDA delays in answering the FOIA requests has subjected approximately 12,926 individuals to an unsupervised non FDA approved experiment causing serious injuries and death.

100. Plaintiff's request for expedited processing concerns a matter of widespread and exceptional interest in which there exists questions about the government's integrity which affects public confidence and continues to place their lives at risk. To date FDA has not provided a response to plaintiff's requests despite detailed explanations and the statutory requirement that all requests even those that don't warrant expedition must be process within 20 working days, [5 U.S.C. 552 (a)(6)(A)(i)].

101. FDA has improperly and/or wrongfully withheld from plaintiff known information and records which are known to be in FDA possession or available to the FDA from the Veterans administration.

102. Notwithstanding the statutory 5 U.S.C. 552 (a)(6)(E)(ii) and regulatory 28 CFR 16.5 (d)(4) time limit of ten calendar days in which to respond to a request for expedited processing, FDA has not responded to Plaintiff's request for expedited processing of any of the FOIA requests.

103. FDA nor any other governmental agency is above statutory law including the failure to act within the time limits constituting exhaustion of administrative remedies with respect to plaintiff's requests as a matter of law pursuant to 5 U.S.C.A. 552 (a)(6)(C).

104. Plaintiff has incurred and will continue to incur expenses for filing this claim.

FREEDOM OF INFORMATION REQUESTS

Closure Medical Corporation Dermabond Adhesive: FOIA *Requests:*
(Without Redaction other than patient and physician names)

a. FOIA *Request*: **Copy of the Closure Medical Corporation PMA, supplemental PMA, or 510(k) FDA filing paper work submitted.** for the "First "*DERMABOND Line Extension Adhesive*" which utilized a new "chisel tip" configuration allowing for a fine-line application as compared to the broad-line application." Ethicon Inc. marketed and placed the new device into commerce, shipping the first quarter 2001 to ("one") retail Closure Medical Corporation Customer, Clomnel Ireland, approximately $9,506,000, million dollar purchase.

b. FOIA *Request:* **Copy of the Closure Medical Corporation PMA, Supplemental PMA, or 510k FDA Filing paper work submitted.** for the new third quarter 2001 unapproved shipment DERMABOND High Viscosity Line Extension "Topical Skin Adhesives", with "chisel tip" applicators. Ethicon Inc. marketed and placed the new high viscosity device into commerce, $4,873,000 million dollars, the third quarter of 2001 to "one" retail customer, Ireland.

c. FOIA *Request:* **February 15, 2001, Copy of Closure Medical's "Filing Paperwork Submitted" for FDA PMA P960052/S001,** Closure Medical Corporation's listing of the exact modifications to clarify safe use of the Dermabond Topical Skin Adhesive.

d. *Request:* **April 4, 2001, Copy Closure Medical's "Filing Paperwork Submitted" for FDA PMA P960052/S002,** including the clarification of use in full detail.

e. FOIA *Request:* **July 24 2002 Copy of Closures Medical's "Filing Paperwork Submitted" for FDA PMA P960052/S005,** Closures Medical Corporation's, complete clarification papers that were submitted for the **change of indication of use** of the adhesive.

f. FOIA *Request;* **The name of the "One" and "Only" "Customer"** Ethicon Inc. and Closure Medical Corporation had 2001, 2002, 2003, 2004, and 2005, purchasing $117,000,000 million dollars or approximately 93% of all non FDA Submitted, non FDA approved, experimental, adulterated, misbranded, off labeled, investigational DERMABOND High Viscosity Line Extension "Topical Skin Adhesive" **with a copy**

of the "Third Quarter" FDA PMA 2001 filing for the first experimental shipment, August 9, 2001, approximately $4,873,000, million dollars.

GUIDANT CORPORATION ADHESIVE FOIA *Requests*
(Without Redaction other than patient and physician names)

g. FOIA *Request:* **February 1, 2001 Copy of Guidant Corporation's "Filing Paperwork Submitted" for FDA PMA P960040/S020,** Listing the Brand of Silicone Adhesive applied as Header Connector Topping and for Bonding Plastic Header to Titanium can wall and a complete listing of *PRIZM AICD Header Modification Made...*

h. FOIA *Request:* **June 27, 2001 Copy of Guidant Corporation's: "Filing Paperwork Submitted" for FDA PMA P960040/S023.** Listing the *brand of Silicone Adhesive* applied as Header Connector Topping and for Bonding Plastic Header to Titanium can wall and type of sterilization process used Clomnel Tipperary, Ireland.

i. FOIA *Request:* **October 26, 2001 Copy of Guidant Corporation's: "Filing Paperwork Submitted" for FDA PMA P960040/S024.** Guidant "Minor Header Modifications" listed for the Prizm II (models 1860 and 1861). Copy of *brand name of Silicone Adhesive* applied as Header Connector Topping and for Bonding Plastic Header to Titanium can wall, and complete list of "Minor" Modifications.

j. FOIA *Request:* **January 22, 2003 Copy Guidant Corporation's: "Filing Paperwork Submitted" for FDA PMA P960052/S005.** Guidant "Minor Changes" to improve silicone insulation in the terminal connector area. **A complete Copy of the "brand" name of the Silicone" applied as Header Connector Topping and for Bonding Plastic Header to Titanium can wall and copy listing of all "Minor Changes" made.**

k. FOIA *Request:* Plaintiff has been informed that certain Guidant employees have stated in 2001 through 2002 that several investigational adhesives were experimented with, including but not limited to the **Nusil Med 4870 and the Rehau SI 1511.**

Plaintiff is *requesting* copies of both the IND's that were filed for the experiments on these two (2) devices including the off labeled use of the adhesives as header connector topping material and bonding material for the header and titanium can wall mounting.

l. FOIA *Request*: **February 2, 2004, (Maude)** A Copy of the actual "Filing Paperwork Submitted" to the FDA "Maude Adverse Event Report" in reference to The Ventak Prizm 2DR 1861 Combination Biological Defibrillator and the following:

Guidant employee Richard Roy's statement:

> "In 2002, guidant became aware that this specific location within the device has the potential to short. Two months later, guidant obtained fda approval and implemented steps in manufacturing to mitigate this issue (eco 40073)."

m. FOIA *Request:* A copy of the Engineering Correction Order ***paper work submitted*** for the FDA February 4 2002 (ECO 40773) by Guidant Corporation.

n. FOIA. *Request:* A copy of the (Guidant employee) Richard Roy's ***paper work submitted***, to the FDA adverse events February 4, 2002 (ECO 40773).

o. FOIA *Request:* ***A copy of the FDA PMA or FDA Supplemental PMA approval*** reported to the Plaintiff by Guidant employee, Daniel Tich, for the February 2002 *changes in adhesive* in the subgroup the Ventak Prizm 2DR 1861 combination biological defibrillators, serial numbers 230796. through 243722 (12,926 devices), ***including the "brand name"*** of the adhesive used.

p. FOIA *Request:* ***A copy of the February 2002 FDA PMA or Supplemental PMA, FDA filed*** approval. Reported to the plaintiff by Guidant employee Daniel Tich, the "Re-routing of the High Voltage Wire" away from the other electrically active components."

q. FOIA *Request:* A copy of the FDA PMA, or Supplemental PMA approval for the extra insulation, and copies of the Guidant paperwork for the 6 months of engineering

efforts to design, validate, acquire, and implement, the submitted documents to the FDA.

r. **FOIA *Request:* A copy of ("Any and All") information, regarding the non FDA approved (6) Ventak Prizm 2DR 1861 Defibrillators listed below.**

105. FOIA Request: **Copies of the *following* "Tracking Documents"** under [Section 519(e)] of the Federal Food Drug, and Cosmetic Act; [21 USC 360i (e)]. Class III Medical device Tracking.

a. FOIA *Request:* Copy of the **tracking method order issued "separately"** by the FDA for the "Brand New" Ventak Prizm 2DR 1861 Combination Biological Device, two Class III unapproved medical devices placed in combination April 16, 2002 through November 13, 2002 as part of the Premarket Clearance process. (serial numbers 230796 through 243722) 12,926 devices.

b. FOIA *Request:* Copy or Name of which of the adhesives were chosen DERMABOND, Nusil Med 4870, or Rehau SI 1511, or other brand, that was in experimental used prior to the fraudulent premarket approval of the 12,926 devices.

c. FOIA *Request:* Copy of the FDA letters issued to the sponsor of the experiments.

d. FOIA *Request:* Copy of the letters notifying the sponsor (Guidant) that the Combination Device should no longer be tracked, with a copy of the publish notice in the Federal Register.

e. FOIA *Request:* Copies of the (6) Listed devices SMDA authority records [21 CFR Part 821] with redacted: SS number, name, address, or any personal information.

f. FOIA *Request:* Copies of variance requested by Guidant in tracking obligations with the (6) "Combination Biological Devices, or any exemptions.

g. FOIA *Request:* Copies of the distributor(s) name, distributor(s) address, Distributor(s) phone and the device locations for the 6 devices. FDA available in 72 hours, 3 working days under {21 CFR 821.25 (a) (1)], for the FDA.

h. FOIA *Request:* Copies of information regarding life sustaining devices (6) each listed use by the single (each) patient, available to the FDA within 10 working days [21 CFR 821.25 (a) (2)].

i. FOIA *Request:* Information listed for the (6) devices under [21 CFR 821.25 (a) (2)] available in 10 working days to the FDA including;

Device identification (lot, batch, model, and serial number;

Date the device was shipped by Guidant for each device;

Date provided to the patient; for implant;

Name of the VA hospital actual implantation was administered;

Name, address, and phone number of the VA Hospital following the patient.

The date of the device explanted, VA Hospital Name, address and telephone, date of the patient death or date device was returned to Guidant or disposed of permanently.

j. FOIA *Request:* Copy of Guidant's 2002 through 2004 tracking audits, FDA provided under MIL STD 105E for the (6) devices, along with copies of any of the non reporting parties of the (6) VA hospitals, under [21 CFR 821.25 (d)].

k. FOIA *Request:* The (6) VA Hospitals, carry the responsibility for collecting, maintain, and reporting back to the manufacturer (Guidant) the required information for tracking of the (6) devices listed, that they received is effective when Guidant distributed the devices and **the VA hospitals are FDA subject to those 6 tracking**

orders. Plaintiff's *FOIA request's* is for copies of FDA general information that was forwarded to Guidant Corporation. The (6) Veteran Hospitals involved have no records of supplying Guidant or anyone else the FDA tracking order information. However Guidant Corporation in June of 2005 stated that the Company had the information from the (6) VA Hospitals.

l. [21 CFR 821.30 (a)] FOIA *Request*: Upon purchasing and acquiring any interest in a tracked Defibrillator, the VA hospital, a final distributor must promptly report to the manufacture (Guidant) the following information: ***We are making a FOIA Request: to the FDA*** for the information copies as the VA Hospitals have informed the Plaintiff, they have no files: FOIA *Request:* A Copy of;

The names of the VA Hospitals and address for each of the 6 devices;

The lot, batch, serial number, and model identifier of the 6 devices;

Dates the (6) devices (Ventak Prizm 2DR 1861 Combination Biological Devices) were received;

Person from whom the device was received; and

The date the device was Explanted Out of use to patient (Date of Death), returned to Guidant Corporation, disposed of permanently or permanently retired from use.

m. FOIA *Request:* [21 CFR 821.30 (a)]; The VA Hospitals, were the final distributors, of the 6 devices listed. These hospitals must make copies of the tracking records available to the FDA upon request. [Subpart D Records and Inspections]; [821.50] issuance of form [FDA 482]; [704 of the act]. The 6 hospitals must make each record and all information required to be collected and maintained. FDA personal for purposes of reviewing, copying, or any other related information to enforcement of the act and this part. Records are required to be kept by this part of the act shall be kept in a centralized point for each distributor within the United States, including the (6) devices, (6) VA Hospitals.

Plaintiff's FOIA Request: for the FDA is to ferret out the 6 devices located at the VA Hospitals and complete the ***Plaintiff's FOIA request*** **by providing a copy of Guidant's Billing for each device and the Veterans Administration reimbursement payment allowing the serial number, VA hospital Name, Guidant billings and amount paid paper or electronic copies as Identifiers.**

Serial Numbers	Implant Date	Ventak Prizm 2DR 1861	Veterans Hospitals
240118	October 8 2002	X	James A. Haley VA
242256	January 16 2003	X	Decatur VA
230863	September 13 2002	X	Audie L.Murphy VA
234219	January 23 2003	X	Portland VA
239693	June 13 2003	X	Denver VA
231388	June 14 2002	X	Louisville VA

106. FDA [821.60]; Persons required to maintain records such as the (6) VA Hospitals on the (6) devices are required to maintain such records for the useful life of each tracked device distributed.

107. The Plaintiff in no way is asking for or causing FDA's privacy regulations to be violated. None of the information being FOIA *requested* is protected by federal privacy regulations. The information requested contains no identifying information on the patients or physicians.

FIRST CAUSE OF ACTION
REFUSAL TO TIMELY RESPOND

108 Plaintiff repeats and alleges allegations contained in paragraphs 1-107.

109 Defendant violated the Freedom of Information Act for failure to Timely Respond to Plaintiff's Requests for Expedited Processing.

110. The failure to timely respond to plaintiff's requests for expedited processing violates FOIA U.S.C.A. 552 (a) (6) (E) (ii) and FDA's regulation promulgated there under 28 CFR 16.5 (d) (4) and was arbitrary, capricious and abuse of the procedures required by law.

111. Defendant violated the Freedom of Information Act for failure to Timely Respond to a Request for Known Agency Records and ferreting out the responsive needs of the plaintiff.

112. FDA's failure to timely respond to Plaintiff's requests for agency records violates the FOIA 5 U.S.C.A. (a) (6) (A) (i) and was arbitrary, capricious and an abuse of the procedure required by law.

SECOND CAUSE OF ACTION
REFUSAL PTPODUCE DOCUMENTS

113. Plaintiff repeats and realleges allegations contained in paragraphs 1-112.

114 Defendant violated the Freedom of Information Act for failure to timely Release FDA Records.

115. FDA's failure to timely release the agency records requested by Plaintiff violates FOIA. 5 U.S.C.A. 552.

RELIEF REQUESTED

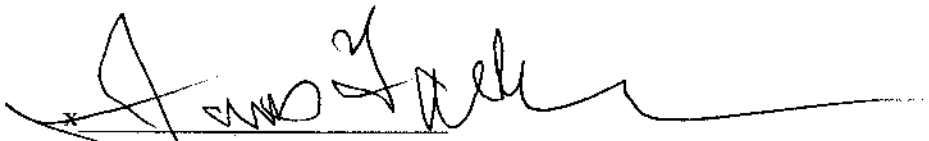
WHEREFORE, Plaintiff prays this Court For:

1. preliminary and final injunction prohibiting Defendant from withholding from Plaintiff the records and documents referred to and described above ***requested;***

2. preliminary and final injunctions directing Defendant to immediately make such records available to Plaintiff and permit the inspection and copying of such documents ***requested;***

3. fees and costs and for such other further relief as the court may seem proper.

Dated: July 22 2009



James F. Allen Director
Patients For Medical Justice, Ltd.
488 Central Avenue
Suite A
Lancaster, New York 14086
Phone 1-716-685-2918